

K043496

510(k) SUMMARY

FEB 16 2005 J. MORITA MFG. CORP.'s
Spaceline Emcia
CU 580

1. Submitter Name and Address with Phone/Fax :

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+81-75-605-2354

2. Contact Person

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. Date summary prepared: October 29, 2004

4. Device Name:

Trade or Proprietary Name: Spaceline Emcia CU 580
Common Name: Dental chair with operative unit

Classification Name: Dental Operative Unit
(21CFR 872.6640)

Product Code : EIA

5. Substantial Equivalency is claimed against the following device:

SIRONA C8 from Sirona Dental Systems, GmgH.
510k # K983242

6. Description of the device:

The CU 580 is a dental treatment Center. It includes a Dental Patient Chair, Dental units a Dental Operating light, and dental operator's stool.

It is designed according to the principles of Home Position Dentistry which a dentist can keep the best posture during an operation.

7. Intended Use

The CU580 is intended for use in general dental applications by providing the dental practitioner a user interface to control operation of the chair and attached dental devices. It delivers air, water, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental office.

It is for use by authorized persons in the practice of dentistry, prosthodontics, oral surgery, orthodontics and oral hygiene.

8. Safety and effectiveness of the device

The CU 580 is substantially equivalent to both the Spaceline Feel 21 (C21) from J.MORITA. MFG. CORP. (K#953865) and the Sirona C8 from SIRONA Dental Systems GmbH (K#983242)..because they have similar general intended uses, technological characteristics and operating principles. Any differences in the technological characteristics do not raise any new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
Fish & Richardson P.C.
1425 K Street N.W. 11th floor
Washington, DC 20005

Re: K043496
Trade/Device Name: SPACELINE EMCIA CU580 Dental Chair with Operative Unit
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: December 16, 2004
Received: December 17, 2004

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

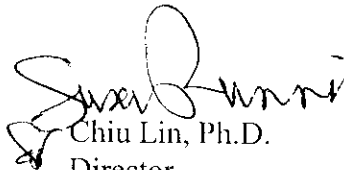
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K#043496

Device Name: SPACELINE EMCIA CU580 Dental Chair with Operative Unit

Indications For Use:

The CU580 is intended for use in general dental applications by providing the dental practitioner a user interface to control operation of the chair and attached dental devices. It delivers air, water, vacuum, and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental office.

It is for use by authorized persons in the practice of dentistry, prosthodontics, oral surgery, orthodontics, and oral hygiene.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Per-Off)
Chief, Anesthesiology, General Hospital
Local Control, Dental Devices

Device Number K043496

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